

Health Literacy & Medication Safety

Overview of Findings & Current Research

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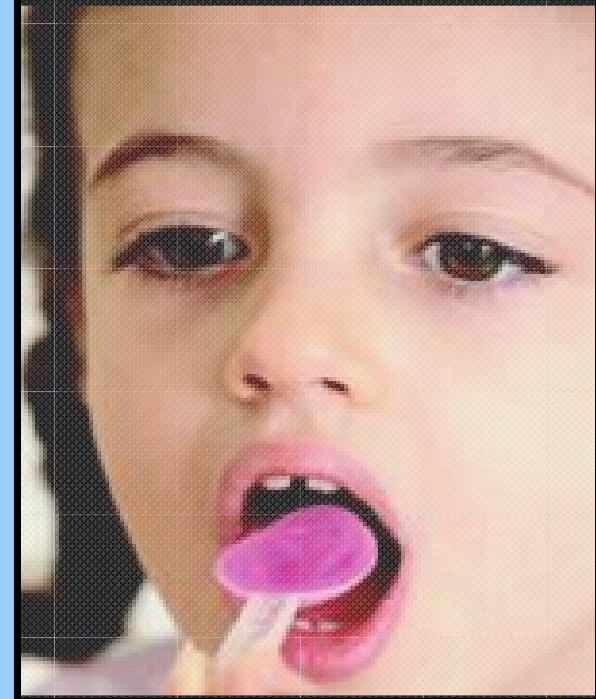
Northwestern University

Medication Error.

- Most common form of medical error.
- > 500,000 *preventable* adverse drug events (ADEs) occur in ambulatory care annually.¹
- Cost: > \$1 Billion/year
- Majority of studies among adults
- Recent surveillance (2001): **250,000** ADEs occur in children and adolescents in outpatient settings annually²
- 1 in 6 children taking an Rx drug will experience a medication dosing error

¹Institute of Medicine, Preventing Medication Error, 2006

²Cohen, Budnitz, Weidenbach, et al. J Ped 2008



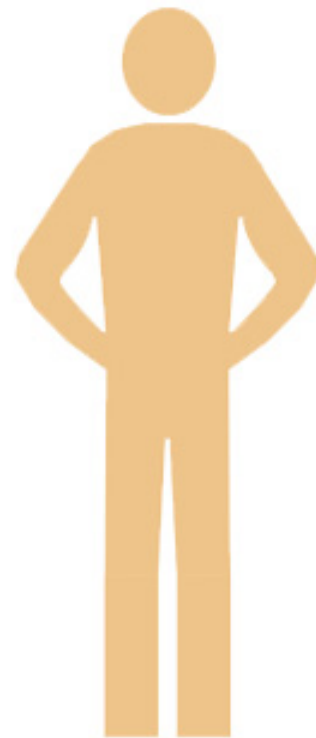
Root Cause – Misunderstanding.

- IOM 2006/2008 reports identifies unintentional misuse a leading root cause
- In outpatient care, patients and their families assume quality control, NOT physicians
- MEPS Data (1996-2003) shows increasing trend – patients of all ages taking more Rx drugs



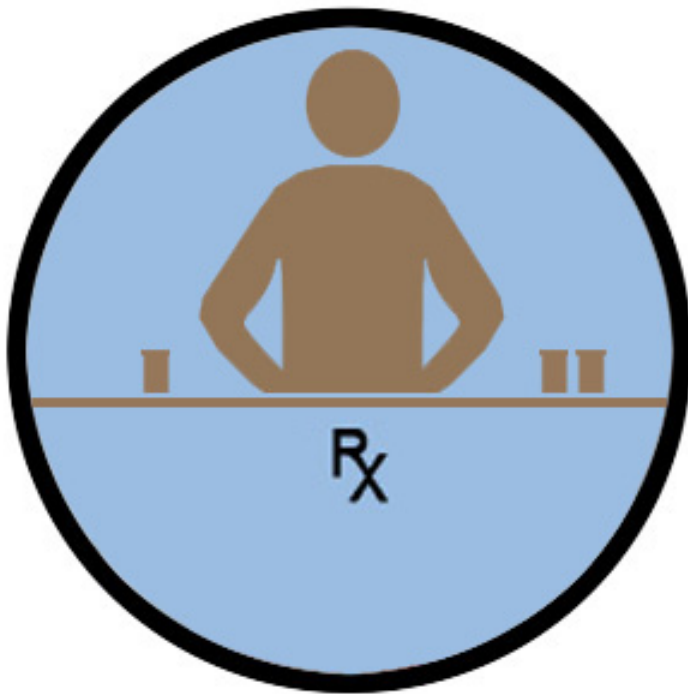
**Do patients and their families
have the necessary skills?**

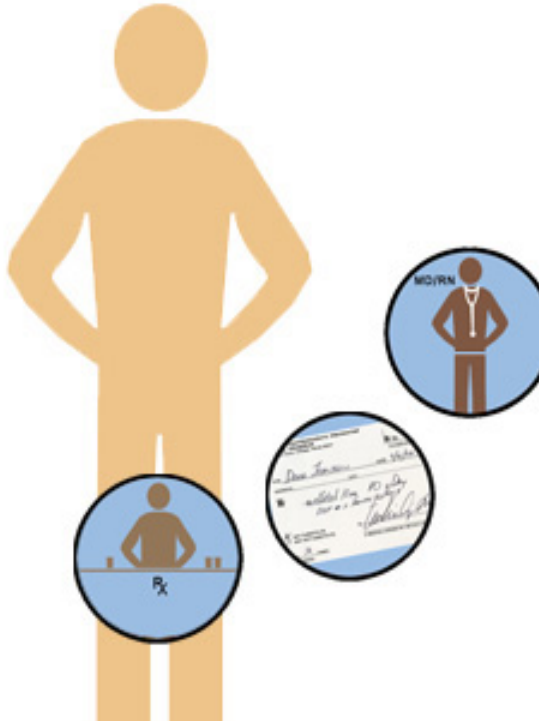


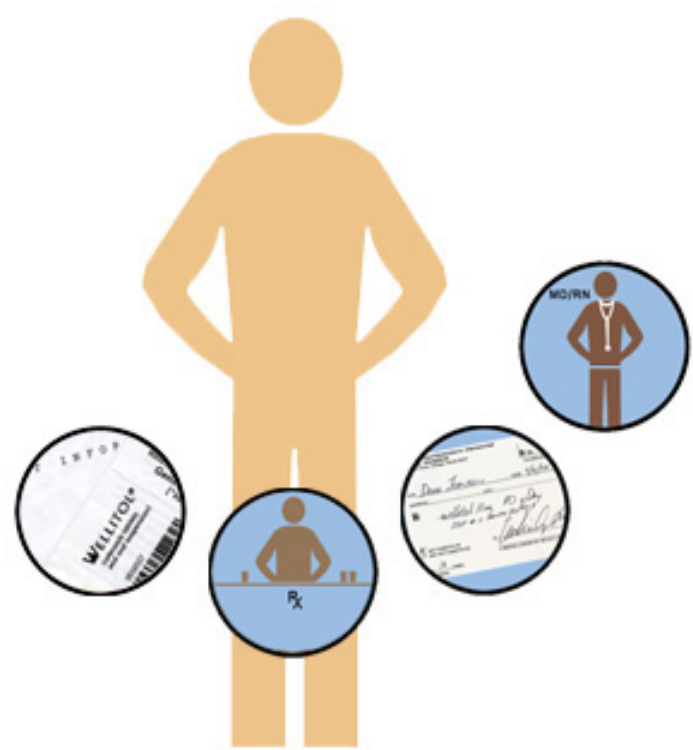


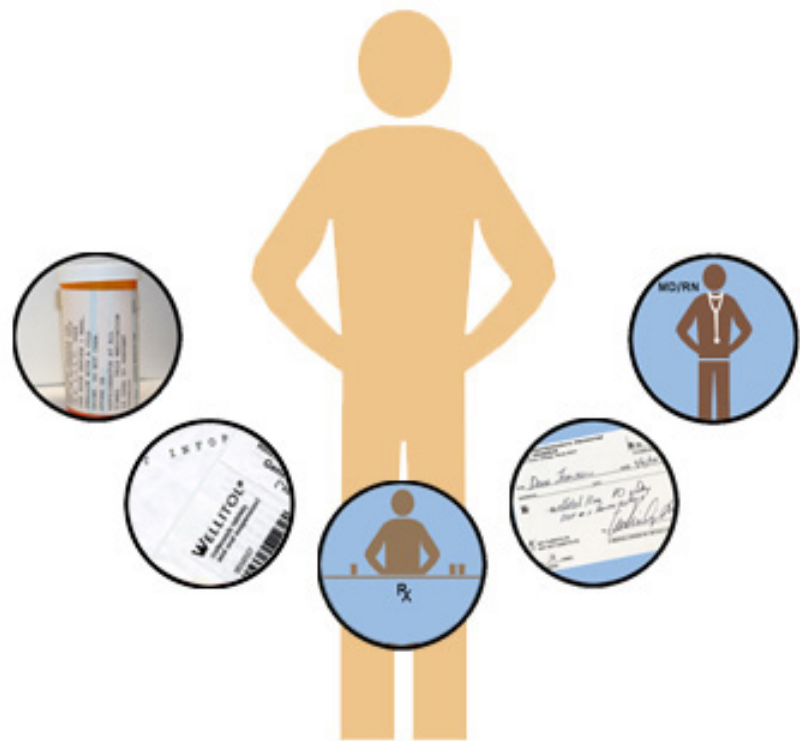




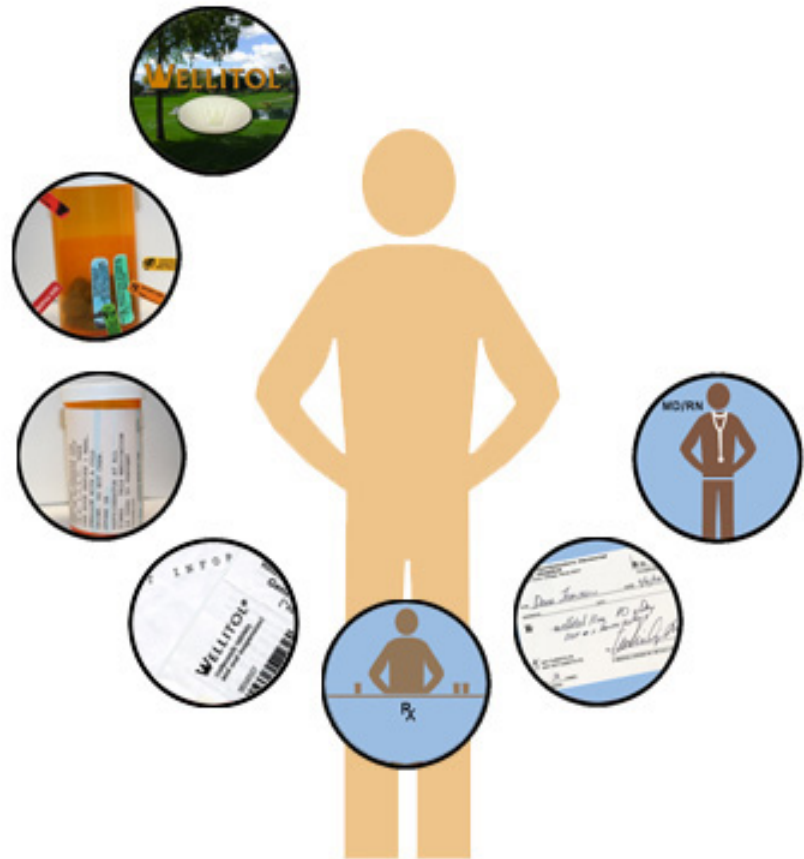




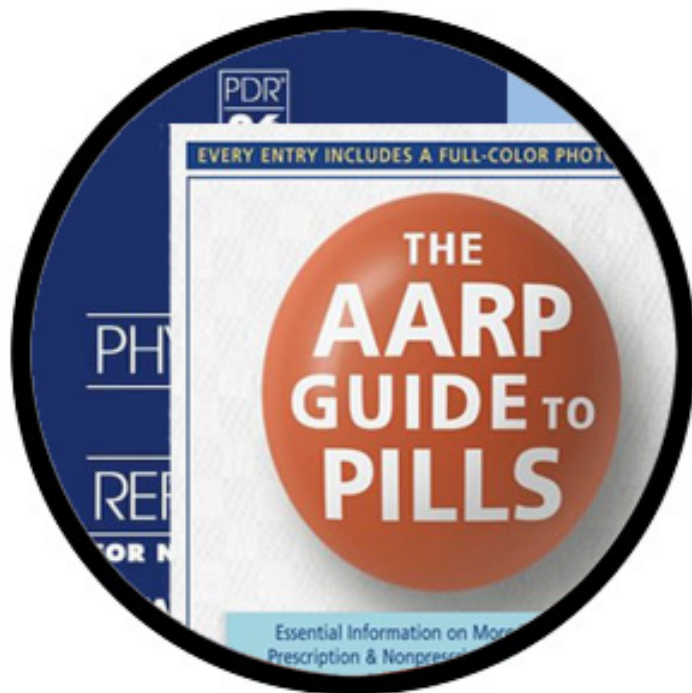


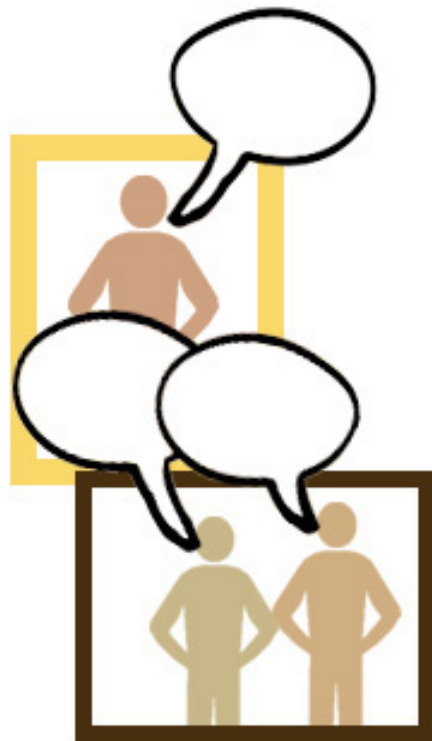






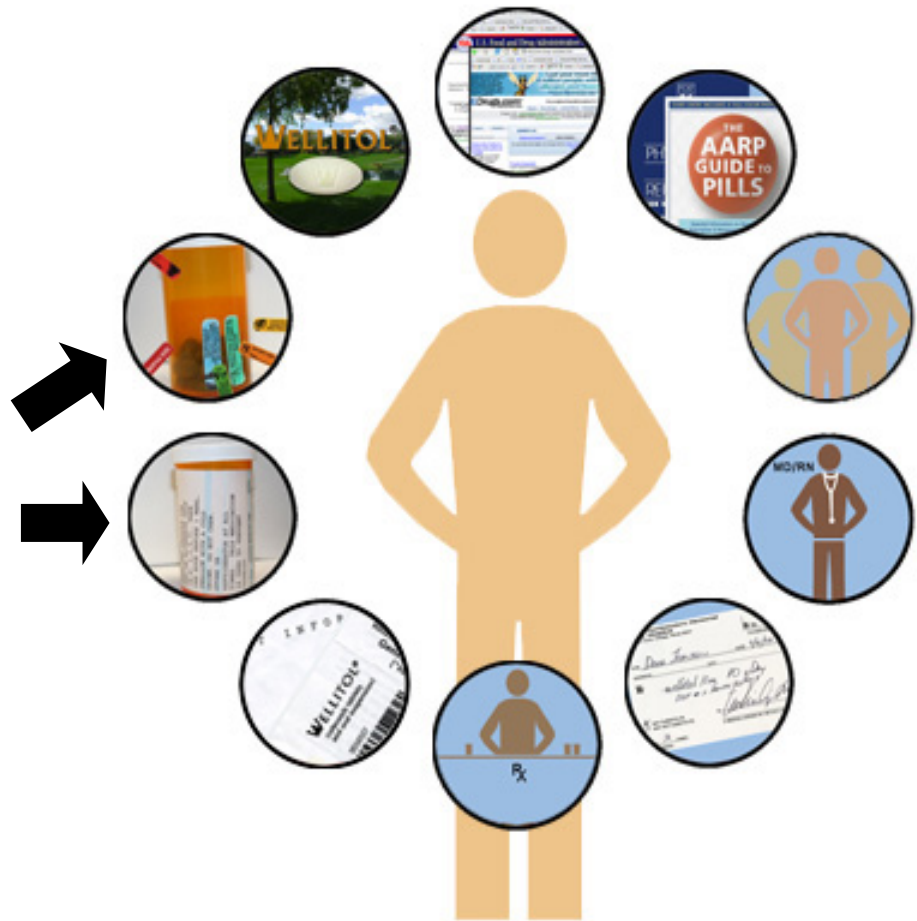






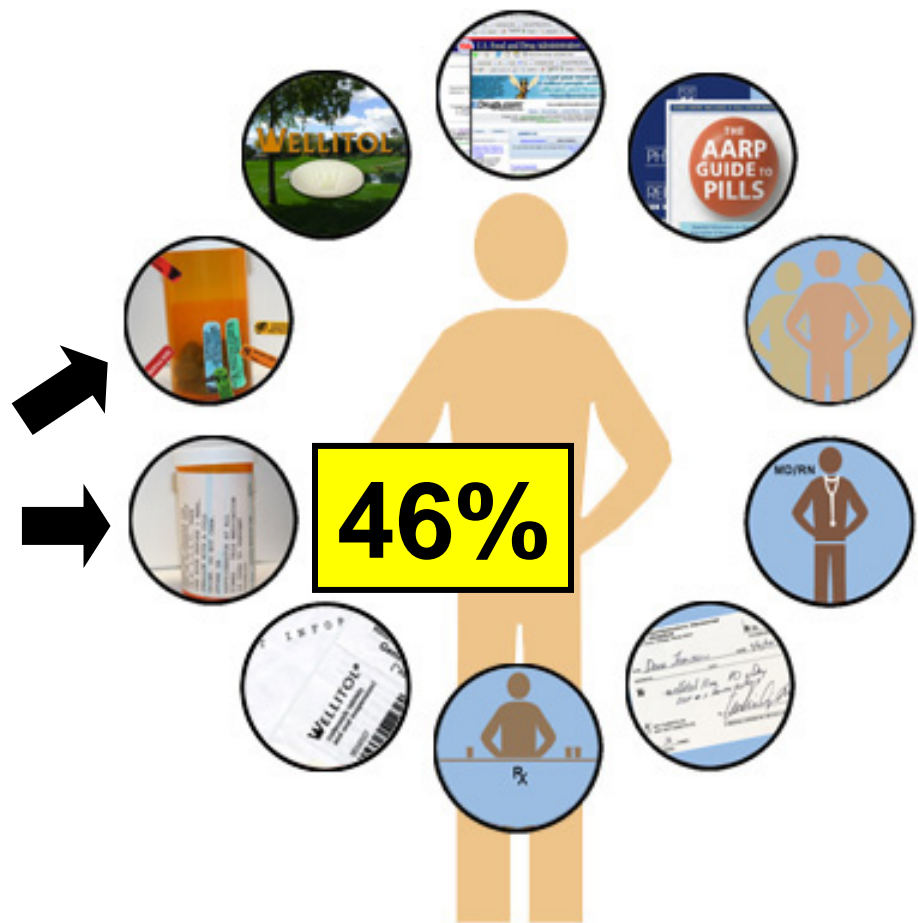
Value of Rx Labels

- Tangible
- Brief
- Repeatedly used
- Only source for many



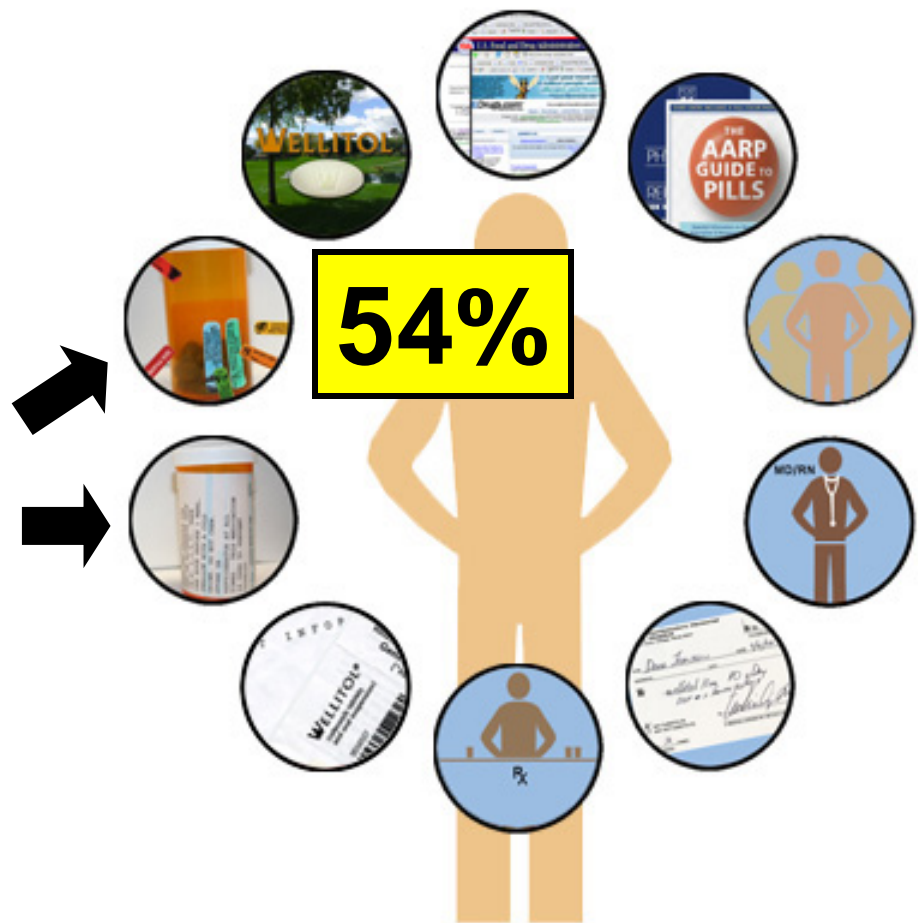
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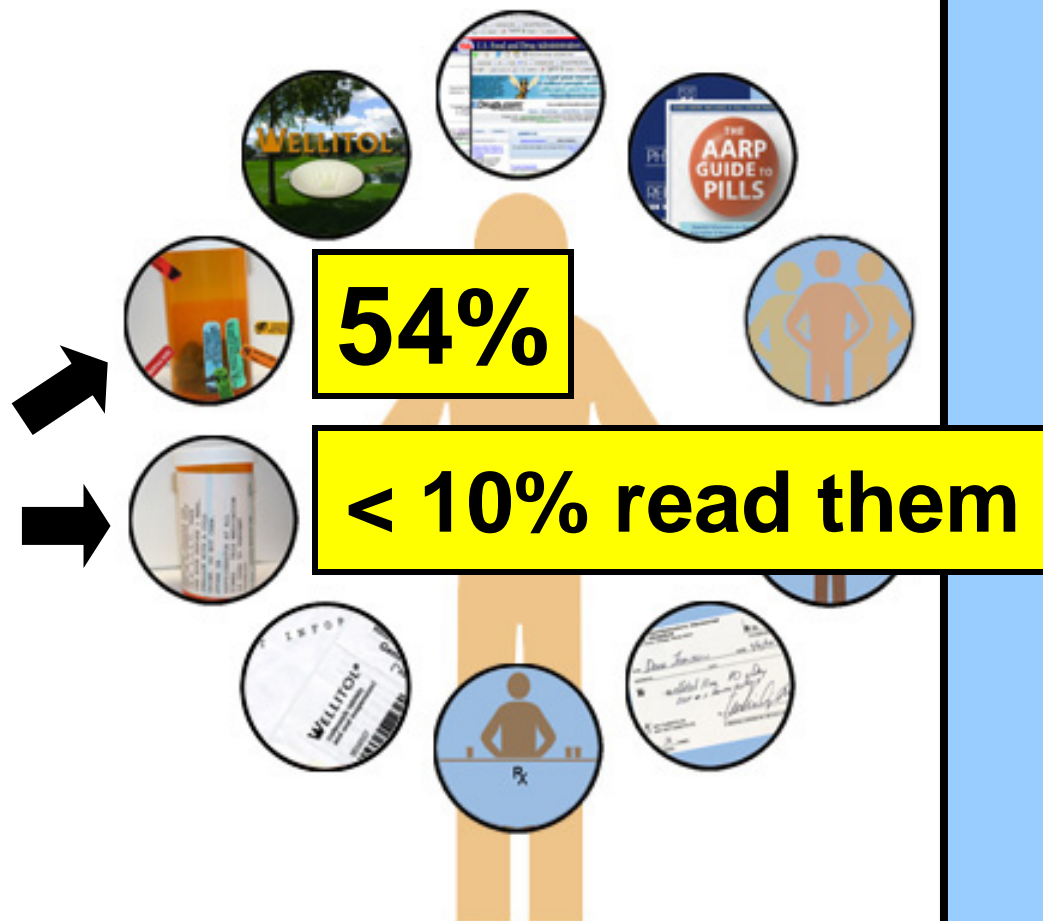
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Beyond the Patient...A Broken System.

- **Minimal federal oversight for Rx drugs**
- **State boards of pharmacy regulate labeling, but currently provide little guidance**
- **Result: variability in prescribing and dispensing of Rx drugs**

Prescribing Variability.

Take one tablet orally once every day.

Take 1 tablet by mouth every morning.

53 Different Ways to Say 'Take 1 Tablet a Day'

Take one tablet for cholesterol .

Take one tablet by mouth once daily.

Take 1 tablet 1 time daily.

Take 1 tablet one time each day.

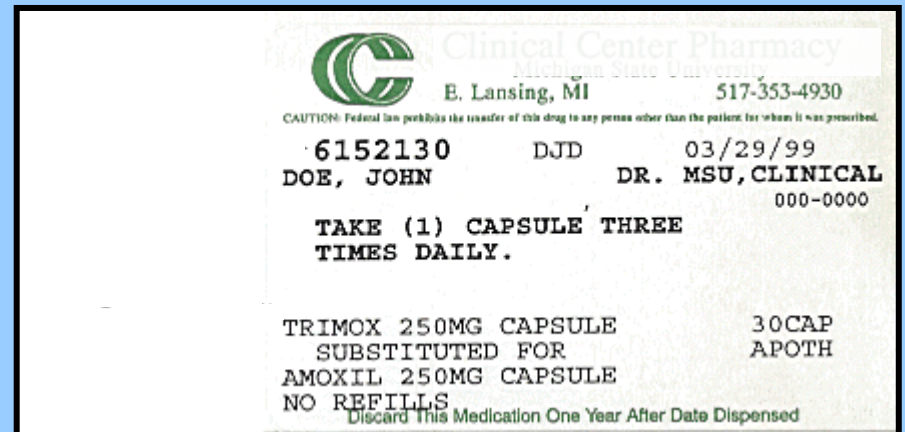
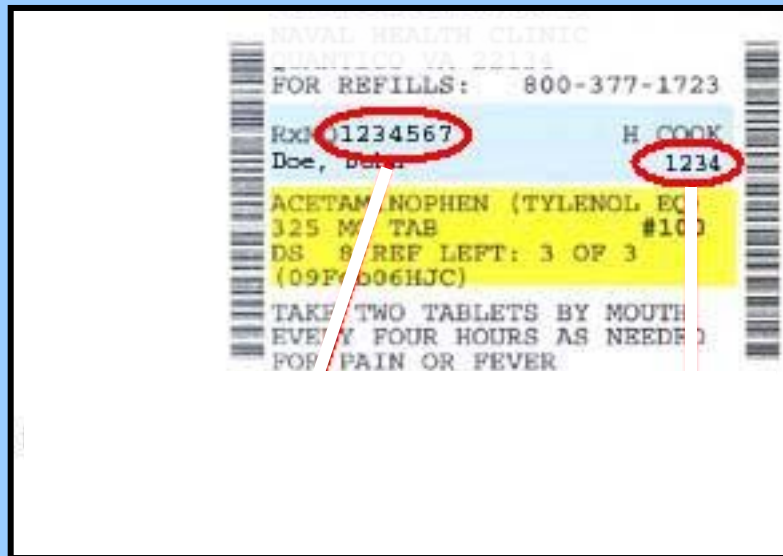
Take one pill by mouth at bedtime.

Take one pill by mouth once each day.

Dispensing Variability.

<p>Lipitor 10 mg tabs</p> <p>Take one tab QD</p> <p>Dispense #30</p> <p>Indication: for high cholesterol</p> <p>No refills</p>	<ul style="list-style-type: none"> - "Take one tablet daily." - "Take 1 tablet by mouth for high cholesterol." - "Take one (1) tablet(s) by mouth once a day." - "Take one tablet by mouth every day for high cholesterol."
<p>Fosamax 5 mg tabs</p> <p>Take one tab QD</p> <p>Dispense #30</p> <p>Indication: osteoporosis prevention</p> <p>Do not lie down for at least 30 minutes</p>	<ul style="list-style-type: none"> - "Take 1 tablet by mouth daily." - "Take one tablet by mouth every day for osteoporosis prevention. Do not lie down for at least 30 minutes after taking." - "Take 1 tablet every day, 30 minutes before breakfast with a glass of water. Do not lie down." - "Take one tablet every day."
<p>Bactrim DS tabs</p> <p>Take one tab BID</p> <p>Dispense #6</p> <p>Indication: UTI</p> <p>No refills</p>	<ul style="list-style-type: none"> - "Take one tablet by mouth twice daily for UTI" - "Take one tablet by mouth twice daily for urinary tract infection." - "Take 1 tablet by mouth 2 times a day." - "Take 1 tablet twice daily for 3 days."
<p>Ibuprofen 200 mg tabs</p> <p>Take 1-2 tabs TID PRN pain</p> <p>Dispense #30</p> <p>No refills</p>	<ul style="list-style-type: none"> - "Take 1 to 2 tablets by mouth as needed for pain." - "Take 1 to 2 tablets by mouth three times daily as needed for pain." - "Take 1 to 2 tablets by mouth as needed for pain ** Not to exceed 4 times a day" - "Take 1 to 2 tablets 3 times a day as needed for pain."

Current Practices not Optimal.



Provider Perspective



Improving Rx Information

Enhanced Rx Label Design

Enhanced Prescription Drug Label Design to Support Patient Understanding and Use
(R01 HS017687-01; PI Wolf)

Overall Objective to test the efficacy of an evidence-based, enhanced prescription drug container label design to improve older patients' understanding of instructions for use.

Methods.

- Actual Use Assessment
- 11 Safety Net Clinics, 1 Central-Fill Pharmacy (Va.)
- Random Assignment to Enhanced vs. Standard Label
- Sample = 960 Diabetic Patients, > 40 years of age
- Assessment: Baseline, 3 months 1 Year
- Outcomes: 1. Functional Understanding
2. Adherence
3. HBA1C

Enhanced Label Prototype

MICHAEL WOLF 04/29/71		Rx #: 1234567 10/30/2008	<ul style="list-style-type: none">• Take with food• Do not drink alcohol while taking this medicine• Limit your time in the sun
GLYBURIDE 5 mg		You have 11 refills 180 pills	
Take for <u>Diabetes</u>		Discard after 10/30/2009	
TAKE 2 PILLS AT BREAKFAST 2 PILLS AT DINNER		Provider: RUTH PARKER, MD Emory Medical Center (414) 123-4567	
Pharmacy: NoVA ScriptsCentral 11445 Sunset Blvd. Reston, VA (713) 123-4567		NDC # 1234567	










Breakfast	Lunch	Dinner	Bedtime
2		2	

Improving Dosage Instructions.

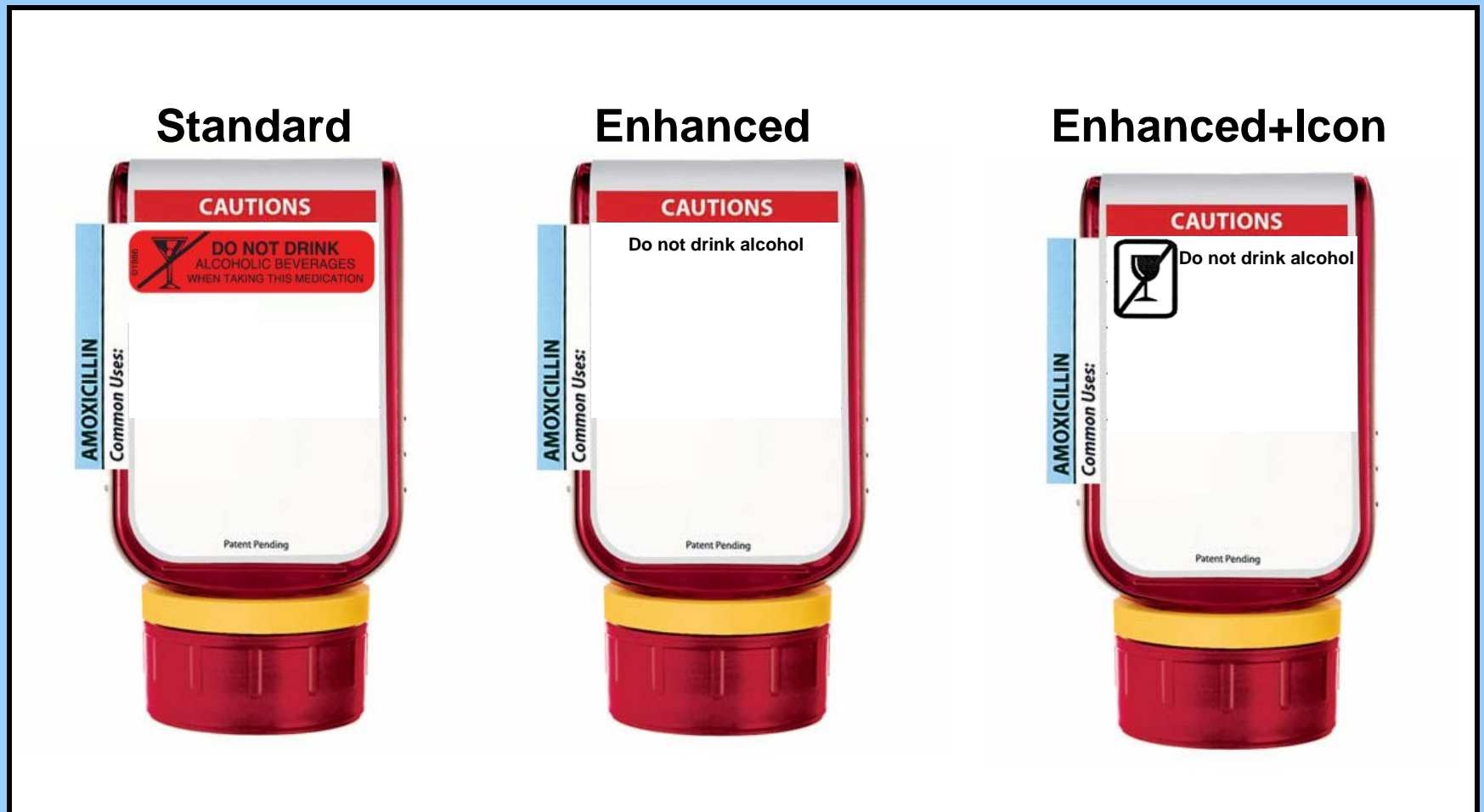
Standard	Enhanced no/UMS	Enhanced w/ UMS								
Take one tablet by mouth daily.	Take 1 tablet at bedtime.	<table><tr><td>Morning</td><td>Noon</td><td>Evening</td><td>Bedtime</td></tr><tr><td colspan="3"></td><td>1</td></tr></table>	Morning	Noon	Evening	Bedtime				1
Morning	Noon	Evening	Bedtime							
			1							
Take one tablet by mouth three times daily.	Take 1 tablet in the morning 1 tablet at noon 1 tablet in the evening	<table><tr><td>Morning</td><td>Noon</td><td>Evening</td><td>Bedtime</td></tr><tr><td>1</td><td>1</td><td>1</td><td></td></tr></table>	Morning	Noon	Evening	Bedtime	1	1	1	
Morning	Noon	Evening	Bedtime							
1	1	1								
Take two tablets by mouth twice daily.	Take 2 tablets in the morning, And 2 tablets at bedtime	<table><tr><td>Morning</td><td>Noon</td><td>Evening</td><td>Bedtime</td></tr><tr><td>2</td><td colspan="2"></td><td>2</td></tr></table>	Morning	Noon	Evening	Bedtime	2			2
Morning	Noon	Evening	Bedtime							
2			2							

Findings.

- 96% of patients correctly interpreted UMS + explicit instructions
- 3x greater comprehension of UMS instructions vs. standard label instructions
(ARR 3.01, 95% CI 1.97 – 4.42)
- Explicit instructions only better than standard, not UMS
(87%; ARR 1.51, 95% CI 1.11 – 2.77)
- Improvement solely on 2 or 3x daily schedules
(40% of US prescriptions)

Original Message	Revised Message	Icon
SHAKE WELL. Before Using.	Shake well before using.	
Warning: Do not use if you are pregnant, suspect that you are pregnant, or while breast feeding. Consult your doctor or pharmacist.	Do not use if you are pregnant, think you are pregnant, or breast feeding.	
Take with food or milk.	Take with food or milk.	
Do not drink alcoholic beverages when taking this medication.	Do not drink alcohol.	
You should avoid prolonged or excessive exposure to direct and/or artificial sunlight while taking this medicine.	Limit your time in the sun.	
For external use ONLY.	Use only on your skin.	
May cause drowsiness. Alcohol may intensify this effect. Use care when operating a car or dangerous machinery.	May cause drowsiness. Be careful when driving a car or using machinery.	
Obtain medical advice before taking nonprescription drugs. Some may affect the action of this medicine.	Talk to your doctor before using any over-the-counter drugs.	
It is very important that you take or use this exactly as directed. Do not skip doses or discontinue unless directed by your doctor.	Do not stop taking unless directed by your doctor.	
To control your blood pressure take regularly, do not continue unless directed by your doctor.		

Improving Rx Warnings.



Summary.

- **Current system of patient Rx info is inadequate**
- **Prescribing/dispensing variability a likely root cause of errors and ADEs**
- **View all aspects of Rx labeling as an integrated system of patient information**
- **Seek improvement, set evidence-based standards**

Support not Replace Physician/Pharmacist Counseling

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